

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

<i>In Re Flint Water Cases,</i>	No. 5:16-cv-10444-JEL-MKM (consolidated) Hon. Judith E. Levy Mag. Mona K. Majzoub
<i>Anderson, et al.,</i> <i>Plaintiffs</i> v. <i>City of Flint, Michigan, et al.,</i> <i>Defendants.</i>	No. 5:17-cv-13890-JEL-MKM

**AFFIDAVIT OF ANDREW CHRISTIAN TODD, Ph.D. AND KARL JOHN
JEPSEN, PhD
REGARDING THE ATTEMPTED CREATION OF A SECOND BONE
LEAD TESTING FACILITY FOR THE PROPOSED FLINT WATER
SETTLEMENT AGREEMENT**

Our names are Andrew Christian Todd, Ph.D. and Karl John Jepsen, PhD. I (Dr. Todd) am a Ph.D. physicist, Research Professor, employed by the Icahn School of Medicine at Mount Sinai, in New York City, in the Department of Environmental Medicine and Public Health. I (Dr. Jepsen) am a Ph.D bioengineer, Professor, employed by the School of Medicine at the University of Michigan in Ann Arbor, in the Department of Orthopaedic Surgery.

Since 1988, I (Dr. Todd) have been involved in the study of bone lead levels.

I (Dr. Todd) was contacted by Ted Leopold and Michael Pitt, regarding what is known as the Flint Water Crisis on 12/21/20. The purpose of that contact was to determine if I could assist in the development of a bone lead testing facility in Flint,



Michigan.

Upon speaking with Messrs. Leopold and Pitt, it seemed best to attempt to replicate the L-shell X-Ray Fluorescence (XRF) method Aaron Specht, Ph.D. was already performing in Flint, MI.

Because of other work commitments (principally the CDC/NIOSH World Trade Center Health Program General Responder Data Center) I (Dr. Todd) am unable to personally perform the actual measurements in the State of Michigan. As such, on 1/7/21, I contacted Dr. Jepsen from the University of Michigan, whom I knew when he was a faculty member at Mount Sinai prior to 2011. Dr. Jepsen agreed to consider establishing a second bone lead testing facility. We were provided a copy of the Bone Lead Testing Program – Flint Michigan, which was co-written by Aaron Specht, PhD of Harvard University and Michael Weitzman, MD of New York University. The document provided general details of the protocol being used in Flint, but lacked critical information needed to replicate the protocol so the outcomes of the two sites would be consistent. We requested a meeting with Dr. Specht to acquire these details.

On January 29, 2021, a videoconference was held that included Hunter Shkolnik, Paul Napoli, Messrs. Leopold and Pitt, several parties from the University of Michigan and Dr. Specht. Special Master Greenspan oriented the scientists to the situation, restated the objective of setting up a second site with bone lead measures that would be consistent with the existing site, and responded to initial questions from some attorneys. The non-scientists then left the call and the scientists began to address the replication of Dr. Specht's method.

It was explained that to obtain comparable results of any testing that might be performed, it would be necessary to obtain the detailed, written protocols Dr. Specht used in his testing regarding this settlement. Without these complete, written protocols including details of the calibration materials and process, it would be impossible to perform testing that would yield comparable results.

Dr. Specht verbally indicated his willingness to help with the replication of his testing by providing the written, detailed protocols he had been and was using in the Flint Water cases. To date, the written, detailed protocols used by Dr. Specht have not been received.

To replicate the test procedure used by Dr. Specht, it was also necessary to obtain the specific XRF analyzers he used and is continuing to use in the tests. As such, Thermo Scientific Portable Analytical Instruments Inc., the manufacturer of

the Niton XL3t 950 GOLDD+ Mining Analyzer, was contacted to see if these could be purchased.

Thermo Scientific Portable Analytical Instruments Inc., through its sales representative, Robert Gillette of Alpha Solutions, Inc, specifically stated they would not sell the XRF device as modified for use by Dr. Specht. Mr. Gillette was contacted because he has general knowledge of the regulatory documents and training needed to safely operate the device, and because he was aware of the modification and use of the XRF device by Dr. Specht in research studies. Mr. Gillette also described a prior situation wherein a faculty member at another university had Thermo buy back this XRF device when Thermo would not provide confirmation that the device was acceptable to use for in vivo testing. As such, there would be no basis for purchasing the devices, particularly without written detailed protocols used by Dr. Specht.

It is our belief that if the XRF analyzer could be purchased with the manufacturer's required modification to prevent the x-ray beam filtration from being changed and the complete methodology used by Dr. Specht could be obtained within the next week, it is not possible at this point to complete the number of bone lead tests that are needed for the Flint community in the time period set forth in the Amended Settlement Agreement.

Anticipated steps needed to establish a second bone lead assessment site: Once the above materials were obtained, contracts would need to be devised and approved to pay for equipment, supplies, personnel, and facilities; the application for registration of the XRF devices would need to be submitted to and approved by the State of Michigan; a safety assessment would need to be conducted on the devices to confirm they are acceptable for in vivo use; a medical doctor licensed in Michigan would need to be recruited to oversee the process, and agree to order the tests and to sign off on the completed tests; an institution providing ethical and safety oversight would need to be secured; written protocols for the testing and the required disclosure/risk documents would need to be drafted and then approved by an Institutional Review Board; a facility providing access to Flint residents would need to be located, and modified and approved for use as an x-ray facility; staff would need to be recruited and hired to work at the facility and then trained to execute the bone lead assessment in a safe and repeatable manner and with regard to best practices for covid-19; a communication plan would need to be devised and implemented to alert Flint residents of the availability of the second test site; and then mechanisms for scheduling and consenting subjects and for analyzing and reporting data in a HIPAA-compliant manner would need to be devised.

The above processes are expected to take many months to complete and before testing could begin in a safe and reliable manner. The mechanics of setting up a safe testing site would put the opening of the facility near the August 26, 2021 deadline for submitting documents to the claims administrator.

Dr. Specht has stated his testing takes three minutes for each person. Estimating conservatively that an appointment would take 15 minutes per person, including consenting, testing, and observing covid-19 guidelines, then approximately 30 persons could be safely tested each day and with the appropriate calibrations. Based on tests conducted 8 hours per day, 5 days per week, and access to 2 XRF devices, we estimate needing more than 4 months to safely test approximately 5000 persons, which was the initial estimate. The total time and costs for these tests would depend on the number of XRF devices that could be purchased and the number of Flint residents that requested testing.

In summary, our attempt to establish a second bone lead assessment site has failed because we have not received written detailed protocols to replicate the existing assessment site, combined with challenges in purchasing XRF devices from a manufacturer that is not willing to confirm the device is acceptable for use on living humans. The fact that the manufacturer is unwilling to stand behind the use of this device on humans would put undue liability on the part of us and our employers, and would potentially expose us to reputational damage which we are unwilling to accept. Given the amount of time that has transpired since we were first contacted, we also believe it is no longer feasible to establish a second site in the timeframe expected for the timely submission of test results. Thus, becoming operational is not feasible given the current deadline for the submission of claims.

Under 28 USC 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on March 25, 2021



Andrew C. Todd, PhD
Research Professor, Mount Sinai



Karl J. Jepsen, PhD
Professor, University of Michigan